

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and the reasons that follow.

Status of the Claims

Claims 67-68 are cancelled without prejudice or disclaimer. Applicant reserves the right to pursue any canceled subject matter in one or more continuing applications with the same rights of priority as the instant application.

Upon entry of these amendments, claims 64-66 and 69-81 will be pending. These claims are presented for reconsideration.

Rejections under §112, Second Paragraph

The §112, second paragraph, rejection of claim 67 was maintained for the reasons set forth at page 3 of the Office Action. While Applicant maintains that there is nothing objectionable about this claim, claim 67 and dependent claim 68 are canceled in order to advance prosecution. Thus, the rejection is moot.

Rejections under §102(e)

Claims 64-68 and 76-81 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Fischer et al. (US 2004/0253310). As pointed out in the previous response, Fischer does not qualify as a prior art reference under 35 U.S.C. § 102(e) because it is not an application filed by “another.” Fischer names the same inventors as the instant application: Gina Fisher, Daniel Bar-Shalom, Lillian Slot and Christine Jensen.

The Office Action states that the rejection is maintained because “Christine Jensen is not the same as Christine Andersen.” While Applicant understands the Examiner’s confusion, Applicant respectfully points out that the Christine Jensen named on the cited Fischer application is indeed “the same person” as the “Christine Andersen” named on this application. This application is a U.S. national phase of a PCT application which named Christine Jensen as an inventor. When executing the Inventors’ Declaration for this U.S.

application, Christine crossed out “Jensen” and replaced it with “Andersen.” Thus, the original Filing Receipt for this application names Christine Andersen as an inventor, but the record makes clear that she is the same person as Christine Jensen.

In further support of this point, Applicant submits herewith a copy of the Decision granting a Petition to change the name of inventor Christine Jensen to Christine Andersen in co-pending application 12/078,312. (No such petition was filed in US 2004/0253310 because that application is abandoned).

In view of the foregoing, Applicant respectfully urges reconsideration and withdrawal of this rejection.

Rejections under §103

The Office Action maintains the obviousness rejection of claims 69-75 based on Fischer (US 2004/0253310) for the same reasons that the anticipation rejection was maintained. As shown above, however, Fischer does not, in fact, qualify as prior art against the instant application, because it is not an application by “another.” Applicant therefore respectfully urges reconsideration and withdrawal of this rejection.

Obviousness-Type Double Patenting Rejections

1. Claims 64-81 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 3-47, and 49-71 of co-pending Application No. 10/550,685 (the ‘685 application). Applicant respectfully traverses this rejection.

As reflected in independent claim 64, the claims pending in this application are directed to therapeutic methods for treating a patient suffering from pain that is sensitive to an opioid, that comprise orally administering an opioid in a controlled release pharmaceutical composition. In contrast, the claims pending in the ‘685 application are directed to controlled release pharmaceutical compositions. Thus, at the outset, fundamental differences between

the claimed subject matter (method vs. composition) weigh against an obviousness-type double patenting rejection.

Moreover, the pending claims are in some ways more narrow and in some ways more broad than the pending '685 claims. For example, while the instant claims recite the use of opioid compositions, the '685 claims are generic as to the identity of the active substance. Further, the '685 claims recite that the composition comprises a poloxamer with an HLB value of at least 18, while the instant claims do not specify the HLB value of the poloxamer that may be present (e.g., in accordance with claim 81).

According to MPEP § 804, "[o]bviousness-type double patenting" arises only when "the claimed subject matter is not patentably distinct." According to MPEP § 806.05(h), "[a] product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process." Where, as here, the compositions recited in the '685 claims can be used in materially different methods (e.g., to treat conditions other than pain that is sensitive to an opioid), the presently claimed methods are patentably distinct from the compositions claimed in the '685 application. Thus, there is no obviousness-type double patenting. Applicant therefore respectfully urges reconsideration and withdrawal of this rejection.

2. Claims 64-81 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 60-100 of co-pending Application No. 12/078,312 (the '312 application). Applicant respectfully traverses this rejection.

Claims 60-96 of the '312 application are directed to controlled release compositions comprising an opioid. (While published claims 97-100 recite methods, these claims have been canceled.) The composition recited in the '312 claims differs from the composition recited in the instant claims in several respects. For example, the '312 claims recite that the composition achieves zero order release of at least about 60% w/w of the active substance when subject to an in vitro dissolution test according to USP 24, NF 19, 711 Dissolution,

employing Apparatus 2 equipped with a paddle, while the claimed methods do not recite zero order release.

Thus, applying the framework set forth in MPEP § 806.05(h), the pending method claims are patentably distinct because they can be practiced with a composition that is materially different from that recited in the '312 claims (e.g., a composition that does not achieve zero order release). Thus, there is no obviousness-type double patenting. Applicant therefore respectfully urges reconsideration and withdrawal of this rejection.

Conclusion

Applicant believes that the application is in condition for allowance, and favorable reconsideration is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution, or if any issues remain that might be resolved by telephone.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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In re Application of :
Fischer, et al. :
Application No. 12/078,312 : DECISION ON PETITION
Filed: 28 March, 2008 :
Attorney Docket No. 028232-0123 :

This is a decision on the renewed petition filed on 28 December, 2009, requesting correction of the name of the inventor/applicant, and considered for relief under 37 C.F.R. §1.182.

The petition under 37 C.F.R. §1.182 is GRANTED.

Petitioners always are directed to the guidance in the Commentary set forth at MPEP§605.04(c) as to the proper procedure herein:

605.04(c) Inventor Changes Name [R-5]

In cases where an inventor's name has been changed after the application has been filed and the inventor desires to change his or her name on the application, he or she must submit a petition under 37 CFR 1.182. Applicants are also strongly encouraged to submit an application data sheet (37 CFR 1.76) showing the new name. The petition should be directed to the attention of the Office of Petitions. The petition must include an appropriate petition fee and **>a statement< signed by the inventor setting forth both names and the procedure whereby the change of name was effected, or a * copy of the court order.

Since amendments are not permitted after the payment of the issue fee (37 CFR 1.312), a petition under 37 CFR 1.182 to change the name of the inventor cannot be granted if filed after the payment of the issue fee.

If an application data sheet is not submitted, the petition may still be granted, but the patent may not reflect the correct spelling of the inventor's name.

If the petition is granted, if the application is maintained in paper with a file jacket label (i.e., the application is an 08/ or earlier series application), the original declaration must be marked in red ink, in the left margin "See paper No. _ for correction of inventor name" and the application should be sent to the Office of Initial Patent Examination (OIPE) for change of name on the file wrapper and in the PALM database. If the petition is granted in an Image File Wrapper (IFW) application or if the application is an 09/ or later series application, the spelling of the inventor's name should be changed in the Office computer records and a new PALM bib-data sheet should be printed. If the application is assigned, applicant should submit a corrected assignment document along with a cover sheet and the recording fee as set forth in 37 CFR 1.21(h) to the Assignment Division for a change in the assignment record.

BACKGROUND

A search of the file indicates that:

The instant application was filed on 28 March, 2008, with an executed oath/declaration in the name of "Christine Jensen"—the name having been typed and signed in that form. Petitions to change that listing to "Christine Andersen," following marriage were filed on 14 November, 2008, dismissed on 30 March, 2009; resubmitted on 22 May, 2009, and dismissed on 28 September, 2009 (Petitioner failed to include with the petition and fee the required declaration by the inventor/applicant, signed in both forms of the inventor/applicant's name—that averred to have been incorrect and that averred to be correct.)

On 28 December, 2009, Petitioner submitted with the petition (and fee previously paid) the required declaration by the inventor/applicant, signed in both forms of the inventor/applicant's name—that averred to have been incorrect and that averred to be correct.

The availability of applications and application papers online to applicants/practitioners who diligently associate their Customer Number with the respective application(s) now provides an applicant/practitioner on-demand information as to events/transactions in an application. Thus, now if one wishes to know the progress in and/or status of an application or the accuracy of the data therein, one need only look at the file online.

Out of an abundance of caution, Petitioners always are reminded that those registered to practice *and* all others who make representations before the Office must inquire into the underlying facts

of representations made to the Office and support averments with the appropriate documentation—since all owe to the Office the continuing duty to disclose.¹

CONCLUSION

The petition under 37 C.F.R. §1.182 is **granted**.

This application is released to the Office of Patent Application Processing (OPAP) with instructions to reflect the correct statement of the inventor's name (formerly known as Christine Jensen) to CHRISTINE ANDERSEN, and to:

- **issue a corrected filing receipt; and**
- **insert into the record the corrected bib sheet,**

and so release the application for further processing in due course.

Telephone inquiries regarding this decision may be directed to the undersigned at (571) 272-3214—it is noted, however, that all practice before the Office is in writing (see: 37 C.F.R. §1.2⁹) and the proper authority for action on any matter in this regard are the statutes (35 U.S.C.), regulations (37 C.F.R.) and the commentary on policy (MPEP). Therefore, no telephone discussion may be controlling or considered authority for Petitioner's action(s).

/John J. Gillon, Jr./
John J. Gillon, Jr.
Senior Attorney
Office of Petitions

¹ See supplement of 17 June, 1999. The Patent and Trademark Office is relying on petitioner's duty of candor and good faith and accepting a statement made by Petitioner. See *Changes to Patent Practice and Procedure*, 62 Fed. Reg. at 53160 and 53178, 1203 *Off. Gaz. Pat. Office* at 88 and 103 (responses to comments 64 and 109)(applicant obligated under 37 C.F.R. §10.18 to inquire into the underlying facts and circumstances when providing statements to the Patent and Trademark Office). See specifically, the regulations at 37 C.F.R. §10.18.

⁹ The regulations at 37 C.F.R. §1.2 provide:

§1.2 Business to be transacted in writing.

All business with the Patent and Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.